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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/486,823 03/03/00 SHIMADA

J EXAMER 38266X00

020457 HM12/0529  
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ART UNIT PAPER NUMBER  
SPIVACK, P 10

DATE MAILED:

05/29/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on MARCH 12, 2001

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire \_\_\_\_\_ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 6-17 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 6-17 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892  
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

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-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Art Unit: 1614

Applicants' Amendment filed March 12, 2001, Paper No. 8, is acknowledged. Original claims 1-5 are canceled. New claims 6-17 are presented and represent all of the claims now under consideration.

A Declaration under 37 CFR 1.132 is further acknowledged wherein compounds of instant formula 1, with  $R_4$  having either furyl or pyridyl, demonstrate neurodegeneration inhibiting activity.

An Information Disclosure Statement filed March 12, 2001, Paper No. 8, is further acknowledged and has been reviewed.

Following the cancellation of claims 1-5, the objection of record under 37 CFR 1.75 (c) and the rejections of record under 35 U.S.C. 112, second paragraph, and 35 U.S.C. 101 are moot. There is no parenthetical subject matter in the newly presented claims. Those substituents contemplated for aryl and heterocyclic groups for the  $R_5$  and Z terms are recited in the newly presented claims.

The disclosure is objected to for the following informalities: In claims 6, 10 and 14 the recitation "wherein n is an integer of 0 to 4" should follow the complete formula  $-(CH_2)_n-R_5$ , as was the case in the originally presented claims.

Appropriate correction is required.

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Claims 1-5 were rejected in the last Office Action under 35 U.S.C. 112, first paragraph, because the specification does not provide enablement for compounds of formula I wherein any heterocyclic group is possible for the R<sub>4</sub> moiety.

In response to this rejection Applicants have submitted the Declaration under 37 CFR 1.132 of Shinichiro Toki. The limitation of the heterocyclic groups in claims 6, 10 and 14 to furyl and pyridyl would be given favorable consideration. The rejection is maintained for reasons of record.

In the last Office Action the claims were rejected under 35 U.S.C. 102(b) as being anticipated by Schweiss et al., U.S. Patent No. 3,641,010. Because Schweiss is not directed to inhibiting neurodegeneration or treating Alzheimer's disease, this rejection of record is withdrawn.

Applicants' arguments with respect to the claims that were rejected under 35 U.S.C. 102(b), as being anticipated by Suzuki et al., U.S. Patent No. 5,484,920 in the last Office Action, have been considered but are moot in view of the new grounds of rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Badger et al., U.S. Patent No. 4,772,607.

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Badger teaches the administration of compounds of instant formula 1, such as, for example, when  $X_1$  and  $X_2$  are O;  $R_1$  and  $R_2$  are lower alkenyl;  $R_3$  is hydrogen;  $R_4$  is  $-(CH_2)_n-R_5$ , and  $R_5$  is phenyl substituted one to three times with hydroxy or alkoxy, in the treatment of Alzheimer's disease. See column 3, line 29. Alzheimer's disease is a degenerative disease of the brain, characterized by clumps of neurofibrils and microscopic brain lesions resulting in progressive loss of mental capacity.

Claims 6, 7, 10, 11, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamoun et al., U.S. Patent No. 5, 173,491.

Kamoun teaches the administration of the compound 1,3,7-trimethyl-8-[3-(4-diethylaminocarbonylpiperizazino)propyl] xanthine hydrochloride, a compound of instant formula 1, to treat Alzheimer's disease, a neurodegenerative condition.

No claim is allowed.

Applicants' Amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number (703) 308-4703.

May 28, 2001

A handwritten signature in black ink that reads "Phyllis Spivack". The signature is written in a cursive, flowing style.

**PHYLLIS SPIVACK  
PRIMARY EXAMINER**